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October 17, 2005

OVERNIGHT COURIER 10/17/05

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned, on behalf of a client, submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("the FDC Act"), 21 U.S.C. § 355(j)(2)(C), and 21 C.F.R. §§ 10.20, 10.30, and 314.93 to request that the Commissioner of Food and Drugs make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Dextroamphetamine Sulfate Tablets USP in strengths of 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs make a determination that Dextroamphetamine Sulfate Tablets, 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg, are suitable for submission as an ANDA. The reference-listed drug product upon which this petition is based is Dexedrine® (Dextroamphetamine Sulfate) Tablets, approved in a 5 mg dosage strength as the reference drug product, NDA Number 84-935, held by GlaxoSmithKline (see Orange Book Listing in Attachment A). Please note that the approved 5 mg RLD is a scored tablet. This petition is submitted for a change in dosage strength from that of the reference drug product.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in strength from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application. This petition requests a change in the strength for the proposed drug from that of the reference-listed drug.

According to the approved labeling of the reference-listed drug product, Dexedrine® (dextroamphetamine sulfate) Tablets, 5 mg, the starting dosage for the management of Narcolepsy and Attention Deficit Disorder with Hyperactivity is listed in the following table:

2005P-0418

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DOSAGE	
Narcolepsy	Usual dose 5 to 60 mg per day in divided doses, depending on the individual patient response.
Attention Deficit Disorder with Hyperactivity	Not recommended for pediatric patients under 3 years of age.
	In pediatric patients from 3 to 5 years of age, start with 2.5 mg daily by tablet; daily dosage may be raised in increments of 2.5 mg at weekly intervals until optimal response is obtained.
	In pediatric patients 6 years of age and older, start with 5 mg once or twice daily; daily dosage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 mg per day.

The proposed package insert for the Dextroamphetamine Sulfate Tablets USP, 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg is consistent with the reference-listed drug labeling. These strengths are within the treatment ranges described in the reference-listed drug labeling and are clearly contemplated doses based on the titration schedule and dosing recommended in the RLD. The availability of the additional strengths will make it easier for physicians to titrate patients to the appropriate dose without requiring the breaking of tablets, and in many cases, will permit dosing with a single tablet, whereas multiple tablets previously had to be relied upon to obtain the desired dose. These factors may improve compliance and patient convenience with prescribed dosing regimens.

In summary, the proposed change in strength of Dextroamphetamine Sulfate Tablets from that of the reference-listed drug (i.e., a change from 5 mg to include strengths of 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg) will not raise questions in safety and efficacy of the proposed product. The indication remains unchanged, and the proposed dosing is consistent with dosing recommendations in the labeling of the approved reference-listed drug product's labeling. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed product will differ from the listed drug only in dosage strength. The indications, route of administration, intended patient population, and recommendations for use will remain the same as for the Dexedrine® Tablet product. Therefore, there should be no question regarding the safety and/or efficacy of the proposed strengths of Dextroamphetamine Sulfate Tablets 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg requested in this petition. The proposed strengths are within the treatment ranges described in the reference-listed drug labeling.

The package insert for Dexedrine® is provided in Attachment B of this petition. The draft package insert for the proposed Dextroamphetamine Sulfate 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg tablet is provided in Attachment C.

C. Environmental Impact

According to 21 C.F.R. § 25.31(a), this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment.

D. Economic Impact Statement

According to 21 C.F.R. § 10.30(b), petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Robert W. Pollock

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RWP/pk

Attachments:

A. Approved Drug Products with Therapeutic Equivalence Evaluations, 24th Edition
B. Dexedrine® (Dextroamphetamine Sulfate 5 mg Tablets) Insert Labeling
C. Draft Insert Labeling for Proposed Drug Product

cc: Arianne Camphire (Office of Generic Drugs)

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